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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,314	02/06/2002	Michael T. Trese	TMT-10902/04	8834

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EXAMINER

DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/068,314

Applicant(s)

TRESE ET AL.

Examiner

Matthew F. DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13-21 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13-21 and 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claims 1 and 14, the range that is being claimed "less than 0.4 to about .01 units" doesn't meet the description requirement because the phrase "about .01 units" fails to set the lower limit within the specific teachings from the specification. The range could be less than .01 units, which is not expressly, implicitly or inherently disclosed in the specification. See MPEP section 2163 (While there is no in haec verba requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.)

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1-7, 9, 10, 13-18, 20, 21, and 24 are under 35 U.S.C. 103(a) as being unpatentable over by Trese et al. (Ophthalmology, Volume 105, Issue 9, 1 September 1998, pages 1617-1620).

Trese et al. discloses the delivery of autologous human plasmin into a vitreous body of an eye and then incubating the eye. Trese et al. discloses using 0.4 IU, but fails to disclose a size of dose smaller than 0.4 IU.

AT the time of the invention it would have been obvious for one of ordinary skill in the art to modify the teachings of Trese et al. because it is well known in the medical field art to vary the dose size that will be injected into a patient, since medication usually depends on the size of the patient as well as the area in which the injection will occur. This concept is well known in the research art and can be seen in the previous cited prior art (Entire reference). There is also a lack of criticality in the range claimed; therefore it would only take routine skill in the art to modify the dose of a medication through routine experimentation.

5. Claims 8, 19, 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trese et al. (Ophthalmology, Volume 105, Issue 9, 1 September 1998, pages 1617-1620) as applied to the claims above, and further in view of Trese et al. (American Academy of Ophthalmology, ISSN 1607-1610).

Trese et al. (Ophthalmology) discloses the claimed invention but fails to specifically point out the use of a plasmin inhibitor and the actual size of the needle being used to remove the liquefaction that occurred in the eye.

Trese et al. (American Academy of Ophthalmology) discloses the use of a plasmin for the liquefaction of the eye as well as the use of small gauge needles for sucking the material out of

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the eye (page 1610 2nd Column, 1st paragraph) and the use of a plasmin inhibitor to reduce to the activity of the plasmin that was injection into the eye (surgical techniques).

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the teachings of Trese et al. with Trese et al. because Trese et al. (American) provides further explanation as to why those steps are necessary. Trese et al. (American) also discloses the level of skill in the medical art since it is well known in the art to perform these steps. Trese et al. (America) provides motivation to use a small gauge so that there will be a smaller hole in the eye from the needle, and the plasmin inhibitor was used to control the amount of time and effectiveness of plasmin.

Response to Arguments

6. Applicant's arguments filed on 5/25/06 have been fully considered but they are not persuasive.

7. The examiner is basing the rejections that it would have been obvious to change the size and concentration of the plasmin that would be injected in an eye due to the lack of criticality of the specific range being claimed. According to MPEP section 2144.05 "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical." Since no such evidence has been submitted the examiner maintains his rejections.

8. The examiner logic of vary the concentration and size of a dose is due to the fact of routine experimentation that occurs when conducting research and treating a patient. This is well known in the medical art and references can be supplied if needed. There are several references of record that disclose varying the concentration to find an optimal range of effectiveness.

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9. The applicant draws the attention of page 5, line 5 in the specification for critical of the 0.4 IU for the invention, but the examiner doesn't find this paragraph to be sufficient because the paragraph teaches varying the dose from subject to subject and that "in a pediatric patient where the volume of the eye is significantly smaller, a dose of 0.4 units may result in facilitating posterior vitreous detachment." There is no support that this dose is critical for treatment or is the optimal dose.

10. With regards to the references teaching away from the claimed invention, the examiner disagrees with the interpretation of the prior art. Both references teach liquefaction of the eye (at least to a certain degree) at an adjacent range to the claimed range. So it would be convincing to perform routine experimentation with the prior art depending on the size of the eye in which the plasmin is going to be delivered. Since the prior art showed some success at 0.4 units and thus wouldn't discourage one of ordinary skill in the art to perform routine experimentation of the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew DeSanto
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January 7, 2007